Message

From: Mendelsohn, Mike [Mendelsohn.Mike@epa.gov]
Sent: 3/31/2020 5:31:44 PM
To: Bohnenblust, Eric [Bohnenblust.Eric@epa.gov]
CC: Reynolds, Alan [Reynolds.Alan@epa.gov]
Subject: FW: Oxitec and GE rule - Internal Deliberative

Eric,

Can you work with Keith and then send me the renegotiation paperwork? Thanks!

Mike

From: Keigwin, Richard <Keigwin.Richard@epa.gov>
Sent: Tuesday, March 31, 2020 1:12 PM
To: McNally, Robert <Mcnally.Robert@epa.gov>; Messina, Edward <Messina.Edward@epa.gov>
Cc: Overstreet, Anne <overstreet.anne@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Subject: RE: Oxitec and GE rule

Internal and Deliberative
Not for Public Release

Ex. 5 Deliberative Process (DP)

From: McNally, Robert <Mcnally.Robert@epa.gov>
Sent: Tuesday, March 31, 2020 9:57 AM
To: Keigwin, Richard <Keigwin.Richard@epa.gov>; Messina, Edward <Messina.Edward@epa.gov>
Cc: Overstreet, Anne <overstreet.anne@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Subject: Oxitec and GE rule

Steps that need to be completed for Oxitec EUP

- 3 Human Health DERs (bioinformatics, and product characterization, arbovirus resubmission) –we may need some additional information from oxitec but this is not yet certain.
- Review of response to latest 75 day letter especially the arbovirus testing information
- Draft Risk Assessment (70% is completed)
- Review of revised section G/experimental program
- Draft response to comment (includes OGC review) (60% completed, has not been sent for OGC review)
- Issuance letter (includes management review)
- Finalize CSF, section G

PRIA Date for Oxitec:

- Regarding a realistic PIRA date, April 30th remains our best estimate, but this could slip with all the back and forth on the GE rule.
- If we temporarily stop working on the rule, an April 23rd decision is reachable. Please realize, however, that Florida is fine with an April 30th completion date.

The gene editing rule:

- Regarding the rule, for us to add a voluntary option will take an 1 additional month.
- For a voluntary option, the scope will be significantly more limited than the mandatory process due to food safety issues and we will need to further communicate with FDA. Describing the more narrow focus of a rule with a voluntary notification approach will take time to adequately insert into the current document.
- On the USTR issues, BPPD has been in contact with Karissa and Ashley in Alex's office and Eric and I are working on their rebuttal of USTR's points.

Definitions:

- We had a discussion Monday with USDA, OMB and other federal agencies to discuss definitional issues. In general, we have a path forward in terms of EPA's role in clarifying definitions and striving for consistency. However, there is one policy issue we need to familiarize you with regarding the pros and cons of defining biotechnology in a way that does limit flexibility for future developers of new technologies.

bob